



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

August 1, 2022

Re: Animal Welfare Assurance
A4051-01 [OLAW Case 1D]

Dr. Wayne Cascio
Director of CPHEA
U.S. Environmental Protection Agency
109 TW Alexander Drive
Durham, NC 27711

Dear Dr. Cascio,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 5, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the U.S. Environmental Protection Agency (EPA) following up on an initial June 24, 2022 notification by telephone.

According to the information provided, this Office understands that the EPA Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to conditions that jeopardized the health/well-being of animals resulting in harm to animals. The final report states a contracted Animal Care Technician (ACT) trained to work with rabbits performed rabbit exercise/play time with two of EPA's 4 rabbits in the RTP vivarium rabbit suite. The New Zealand White rabbits were placed into separate play pens within the same room as per the vivarium OP. On June 16th, these rabbits were placed inside play pens at 10:15am and removed by 1:30pm. The animals were checked three times during this period. It is stated on the last check the ACT discovered both rabbits in the same pen with minor injuries. Both play pens were still closed with no sign of forced entry.

One rabbit was reported for an abrasion and scratch on the ear with no bleeding or discharge. The other animal was reported for a broken nail on "the right front and right back foot" per the Animal Health Report, also no bleeding or discharge present. After the veterinarian and veterinary technician assessed the animals, an email report was sent to the Principal Investigator, laboratory staff, Attending Veterinarian, and other individuals. In response, the veterinarian suspended use of the exercise pens until the root cause for the incident was eliminated. It is understood both animals are doing well, and treatment continues for the ear wound.

An in-depth investigation determined the ACT followed the SOP appropriately. However, a lack of engineering controls was identified that could allow rabbits to co-mingle. The controls were identified as the following:

- Rabbits outside of the home cage should not be left unsupervised.
- The gate to each play pen was extremely easy to open. A rabbit could nudge the bottom of the gate with its nose, and it would open. These gates can also swing closed.
- The play pens are designed to be connected into a circle or a square. In this instance, they were made into a semi-circle or square with the concrete holding room wall as the fourth side of the pen. Since the pen was not connected, a rabbit could push the pen wall away from the concrete wall to escape the play pen.

- A cardboard box was added to each play pen as a form of enrichment. It is possible that a rabbit could use the box to jump to the adjacent pen.
- Cleanable covers can be purchased for play pens.

In response to these findings, EPA-RTP will address the following engineering controls:

- The OP will be modified to state animals may not be left unsupervised when they are out of their home cages.
- Gates will have additional latches.
- The playpens will be moved into separate rooms.
- The program will consider if a cover needs to be purchased or if a different type of enrichment should be used.

It is understood hands-on retraining of staff regarding rabbit care, exercising/enrichment program, and emergency procedures is being considered. However, since the staff working with rabbits have been extensively trained (with no prior reports), and performed care duties as per the OP, the value of this training is being debated. While the final report classified this incident as an adverse event, OLAW considers this incident a noncompliance since appropriate engineering controls (that were identified as missing) most likely would have prevented this incident.

Based on its assessment of this explanation, OLAW understands that the U.S. Environmental Protection Agency has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

**Jacquelyn
T. Tubbs -S**

Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2022.08.01
15:43:46 -04'00'

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Monday, August 1, 2022 3:47 PM
To: Cascio.wayne@epa.gov
Cc: OLAW Division of Compliance Oversight (NIH/OD); Gavett.Stephen@epa.gov; graff.jaimie@epa.gov
Subject: OLAW Case A4051-1D
Attachments: A4051-1D.pdf

Good afternoon Dr. Cascio,

Attached please find Dr. Tubbs' final response to OLAW Case A4051-1D. If you have any questions, feel free to contact us by phone or by e-mail.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
CENTER FOR PUBLIC HEALTH AND ENVIRONMENTAL ASSESSMENT
Research Triangle Park, NC 27711

OFFICE OF
RESEARCH AND DEVELOPMENT

July 5, 2022

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare
National Institutes of Health

Dear Dr. Wolff:

We are writing to report the final resolution of an adverse animal welfare incident at the US EPA Research Triangle Park (RTP) research program, USDA Certificate number 55-F-0001, Customer ID number 962; PHS Assurance # D16-00569, A4051-01; AAALAC Unit #000509, including measures taken by the program to ensure that these events will not be repeated. A preliminary report of this event was originally submitted to the USDA and AAALAC by email and by voice mail to OLAW on Friday, June 24.

A contracted Animal Care Technician (ACT) specifically trained to work with the rabbits was performing rabbit exercise/play time with two of EPA's four rabbits in the RTP vivarium rabbit suite. Both rabbits are New Zealand Whites, intact males, and are known to each other. The rabbits were placed into separate play pens within the same room as directed by the vivarium OP. The play pens have been in use for several years now and were praised by the facility's 2020 AAALAC site visitors. The OP is updated at least annually. According to the Rabbit Play Pen Log on Wednesday, June 16, these rabbits were placed into the play pens at 10:15am and removed by 1:30pm. The technician performed checks of the rabbits at 11:10am 12:15pm, and 1:23pm. On the last check the ACT found both rabbits in the same pen together, lying beside each other a little out of breath with minor injuries. Both rabbit pens were still closed with no sign of forced entry.

Animal Health Reports were generated for both rabbits. One rabbit, Doc, was reported at 12:45pm for "Right ear abrasion on inside and scratched on outside from fighting with Jasper". On the report the animal care technician noted that the animal did not appear to be suffering. The animal did not have any bleeding or discharge. The other rabbit, Jasper, was reported at 1:22pm for "broken nail on right front and right back foot". On the report the animal care technician noted that the animal did not appear to be suffering. The animal did not appear to have any bleeding or discharge.

An email report was sent to the PI and lab staff, Attending Veterinarian, Vet Technician, Animal Resources Program Office, via the animal care office later that afternoon, after the veterinarian and veterinary technician assessed the animals.

The veterinarian has suspended use of the exercise pens until the potential for the rabbits getting into the same play pen is eliminated.

According to the most recent treatment report both rabbits are BARH (Bright, Alert, Responsive and Hydrated). Doc continues treatment for the wounds on his ear.

The vivarium manager who conducted an in-depth investigation began work at the EPA/RTP vivarium on June 21, replacing a vivarium manager who was dismissed on June 13 for unrelated causes, and was not present for the June 16 incident. In their investigation they determined that the animal care technician followed the SOP appropriately. They also reviewed the play pens and saw lack of engineering controls that could allow rabbits to become co-mingled. These controls are as follows:

1. Rabbits outside of the home cage should not be left unsupervised.
2. The gate to each play pen was extremely easy to open. A rabbit could nudge the bottom of the gate with its nose, and it would open. These gates can also swing closed.
3. The play pens are designed to be connected into a circle or a square. In this instance they were made into a semi-circle or square with the concrete holding room wall as the fourth side of the pen. With the pen not being connected, a rabbit could push the pen wall away from the concrete wall to escape the play pen.
4. A cardboard box was added to each play pen as a form of enrichment. It is possible that a rabbit could use the box to jump to the adjacent pen.
 - a. Cleanable covers can be purchased for play pens.

The EPA RTP vivarium staff will address these engineering controls.

1. The OP will be modified so that it is clear that the animals may not be left unsupervised when they are out of their home cages.
2. Gates will have additional latches.
3. The playpens will be moved into separate rooms.
4. The program will consider if a cover needs to be purchased or if a different type of enrichment should be used.

The program is also considering the following:

1. Hands on retraining of staff that covers basic rabbit care, exercising and enrichment program, and emergency procedures. The utility of this training is being debated, since the staff working with the rabbits have all been trained extensively, have worked with the rabbits for years with no prior reports, and were performing care duties according to the OP.

We hope these measures satisfactorily address the issues raised by this incident. Please contact Stephen Gavett ((b) (6) Gavett.stephen@epa.gov) or Jaimie Graff ((b) (6) Graff.jaimie@epa.gov), Animal Resources Program Office, if you have further questions.

Sincerely,

(b) (6)

Wayne E. Cascio, M.D.
Director, CPHEA
Institutional Official

(b) (6)

Stephen H. Gavett, Ph.D., D.A.B.T.
CPHEA / PHITD / CIB
IACUC Chair

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, July 8, 2022 7:05 AM
To: Graff, Jaimie
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final report of adverse event, Assurance D16-00569

Thank you for this report. We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Graff, Jaimie <Graff.Jaimie@epa.gov>
Sent: Wednesday, July 6, 2022 11:09 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] Final report of adverse event, Assurance D16-00569

Good afternoon;
Attached please find a final report of an adverse event for US EPA's ORD RTP animal care and use program, Assurance D16-00569, following an voicemail report on June 24, 2022.
Please call or email me if you have any questions.
Thank you;
Jaimie Graff

Jaimie Graff, MA, CPIA | Director, Animal Resources Program Office | US EPA/ORM/RSCD/FRCB | Phone: (b) (6)
Cell: (b) (6)

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Initial Report of Noncompliance

By: BCM

Date: 6/24/2022

Time: 9:30

Name of Person reporting: Jamie Graff

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: US EPA RTP

Assurance number: A4051-1D

Did incident involve PHS funded activity? ?

Funding component:

Was funding component contacted (if necessary):

What happened?

Two male rabbits placed together. Some fight wounds and injured ears.

Species involved: Rabbits

Personnel involved: ?

Dates and times: ?

Animal deaths: no

Projected plan and schedule for correction/prevention (if known):

Investigating. Will report to IACUC.

Projected submission to OLAW of final report from Institutional Official:

< 60 days

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Case #